IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA Plaintiff, v. MORIN ENTERPRISES, INC., d/b/a E-CIG CRIB, a corporation, and KEVIN MORIN, an individual, Defendants.	Civil No. 22-cv-2592 **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to permanently enjoin Morin Enterprises, Inc., d/b/a E-Cig Crib ("Morin" or "the company"), a corporation, and Kevin Morin, an individual, from violating 21 U.S.C. § 331(k), by causing tobacco products, within the meaning of 21 U.S.C. § 321(rr), to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant Morin is a Minnesota corporation with a registered office address at 230 Dewey Street, Mankato, MN 56001, within the jurisdiction of this court. The company has had two locations from which it conducts or has conducted its tobacco product operations: 3027 Coon Rapids Blvd NW, Coon Rapids, MN 55433 ("Coon Rapids facility") and 1730 Madison Ave., Mankato, MN 56001 ("Mankato facility").

5. Defendant Kevin Morin is Morin's Chief Executive Office and sole owner, and the most responsible individual at the company.

6. Defendant Kevin Morin performs his duties at the Coon Rapids facility and/or the Mankato facility, within the jurisdiction of this Court.

Defendants' Operations

7. Defendants manufacture finished electronic nicotine delivery system ("ENDS") products, including finished e-liquids under the E-Cig Crib brand ("Defendants' ENDS products" or "their ENDS products"), at the Coon Rapids facility, and Mankato facility. Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products. From these facilities, Defendants also sell and distribute

their ENDS products, and ENDS products manufactured by others, to individuals for personal consumption.

Defendants' ENDS Products Are Adulterated and Misbranded

8. Defendants violate the FDCA by causing tobacco products to become adulterated or misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. 21 U.S.C. § 331(k).

Defendants' ENDS Products Are Tobacco Products

9. The FDCA defines "tobacco product" at 21 U.S.C. § 321(rr) to include "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." A "tobacco product" within the meaning of 21 U.S.C. § 321(rr) is generally subject to the requirements in 21 U.S.C. Chapter 9, Subchapter IX. *See* 21 U.S.C. § 387a(b) (providing that such subchapter shall apply to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that [FDA] by regulation deems to be subject to this subchapter"); 81 Fed. Reg. 28974, 28975 (May 10, 2016) (deeming all products meeting the definition of "tobacco product" at 21 U.S.C. § 321(rr), except accessories of such newly deemed products, to be subject to such subchapter).

10. ENDS products generally meet the definition of "tobacco product" at 21 U.S.C. § 321(rr), and include: "devices, components, and/or parts that deliver aerosolized e-liquid when inhaled." FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market*

*Without Premarket Authorization (Revised)** (Apr. 2020), 9–10, https://go.usa.gov/xuvn5. E-liquids "are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients)." *Id.*

11. Defendants' ENDS products are made or derived from tobacco, or contain nicotine from any source, and are intended for human consumption, and thus are "tobacco product[s]" within the meaning of 21 U.S.C. § 321(rr).

Defendants' ENDS Products Are New Tobacco Products

12. The FDCA defines "new tobacco product" at 21 U.S.C. § 387j(a)(1) to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007."

13. Defendants' ENDS products were not commercially marketed in the United States as of February 15, 2007, and thus are "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1).

Pathways to Market for New Tobacco Products

14. A new tobacco product may receive FDA marketing authorization through any one of three pathways: (1) the premarket tobacco product application ("PMTA") pathway under 21 U.S.C. § 387j, through which FDA reviews a PMTA and issues an order permitting marketing of the new tobacco product ("MGO") under 21 U.S.C. § 387j(c)(1)(A)(i) upon a finding that the product is appropriate for the protection of the public health; (2) the substantial equivalence ("SE") pathway under 21 U.S.C. § 387j(a)(2)(A)(i), through which FDA reviews a report submitted under 21 U.S.C.

§ 387e(j) ("SE report") for the product and issues an order determining, among other things, that it is substantially equivalent to a tobacco product commercially marketed in the U.S. as of February 15, 2007, or a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent ("SE order"); or (3) the SE exemption pathway under 21 U.S.C. § 387j(a)(2)(A)(ii), through which FDA reviews an exemption request submitted under 21 C.F.R. § 1107.1 and a report submitted under 21 U.S.C. § 387e(j)(1) ("abbreviated report") for the product, and issues a "found-exempt" order pursuant to 21 U.S.C. § 387e(j)(3)(A).

15. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i), is adulterated under 21 U.S.C. § 387b(6)(A). A new tobacco product is required by 21 U.S.C. § 387j(a) to have premarket review, unless it has an SE order or found-exempt order in effect. *See* 21 U.S.C. § 387j(a)(2)(A).

16. A new tobacco product for which a "notice or other information respecting it was not provided as required" under the SE or SE exemption pathway, including an SE report or an abbreviated report, is misbranded under 21 U.S.C. § 387c(a)(6).

Defendants' ENDS Products Have Not Been Authorized by FDA and Are Both Adulterated and Misbranded

17. Defendants' ENDS products, as "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1), are required by 21 U.S.C. § 387j(a) to have premarket review, as they do not have an SE order or found-exempt order in effect. Defendants'

ENDS products do not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i). Accordingly, Defendants' ENDS products are adulterated under 21 U.S.C. § 387b(6)(A).

18. In addition, neither an SE report nor an abbreviated report has been submitted for any of Defendants' ENDS products. Accordingly, Defendants' ENDS products are misbranded under 21 U.S.C. § 387c(a)(6).

Defendants Engage in Interstate Commerce

19. Defendants hold their ENDS products for sale after shipment of their components in interstate commerce. Specifically, the flavors (e.g., cotton candy, watermelon) that Defendants use to make their ENDS products come from California.

Defendants' History of Violative Conduct

20. Defendants are aware that their practices violate the FDCA. FDA has warned Defendants about their violative conduct and explained that continued violations could lead to enforcement action, including an injunction.

21. After conducting a review of Morin's website, FDA sent Defendants a Warning Letter on March 26, 2021. The Warning Letter informed Defendants that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization, including certain finished e-liquid products under the E-Cig Crib brand. The Warning Letter further cautioned that such products are adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6), and that Defendants' failure to address their violations of the FDCA relating to tobacco products could lead to enforcement action, including an injunction.

22. On April 8, 2021, FDA held a teleconference with Defendant Kevin Morin, to answer any questions regarding the violations cited in the Warning Letter. During the teleconference, Defendant Kevin Morin stated that, to address such violations, he would contact a disposal company to immediately destroy all of Defendants' adulterated and misbranded tobacco products. In a letter to FDA dated that same day ("Warning Letter Response"), Defendant Kevin Morin stated that by April 15, 2021, Defendants would destroy all finished e-liquid products under the E-Cig Crib brand and stop manufacturing violative products.

23. FDA attempted to contact Defendant Kevin Morin several times after receiving the Warning Letter Response—by email on July 30, 2021, and by phone on August 3 and September 2, 2021—to confirm that Defendants had completed the promised corrective actions. Defendant Kevin Morin did not respond to any of these communication attempts.

24. FDA inspected Defendants' Coon Rapids facility between March 22 and 24, 2022. During this inspection, FDA investigators observed that Defendants continued to manufacture, sell, and distribute new tobacco products, including finished e-liquid products under the E-Cig Crib brand, that lacked required FDA authorization, in violation of the FDCA. At the close of the inspection, FDA investigators discussed these violations with Defendant Kevin Morin, and other company officers, and reminded them of their responsibility to ensure compliance with the FDCA. Defendants did not promise any corrective actions that would resolve these violations during the inspection, and Defendants have not contacted FDA since then.

Request for Relief

25. Despite numerous notifications, Defendants remain unable or unwilling to comply with the FDCA. Unless restrained by this Court, Defendants will continue to violate the FDCA in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing a violation of 21 U.S.C. § 331(k), by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce;

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the manufacture, sale, and distribution of tobacco products, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. Award Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated: October 18, 2022

Respectfully submitted,

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